

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION**

NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,
MITSUBISHI TANABE PHARMA
CORPORATION, and MITSUI SUGAR
CO., LTD.

Plaintiffs,

v.

EZRA VENTURES, LLC

Defendant.

Case No. 4:15-cv-00095-KGB

PLAINTIFFS' ANSWER TO EZRA'S COUNTERCLAIMS

Plaintiffs Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation, and Mitsui Sugar Co., Ltd. (collectively, "Plaintiffs") by their attorneys, respond to the Counterclaims of Ezra Ventures LLC ("Ezra") as follows:

THE PARTIES

1. Upon information and belief, the allegations of Paragraph 1 of the Counterclaim are admitted.

2. The allegations of Paragraph 2 of the Counterclaim are admitted.

3. The allegations of Paragraph 3 of the Counterclaim are admitted.

4. It is admitted that MTPC is a corporation organized and existing under the laws of Japan but denied that MTPC has an office and place of business at 2-6-18, Kitahama,

Chuo-ku, Osaka 541-8505, Japan. MTPC has an office and place of business at 3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan.

5. The allegations of Paragraph 5 of the Counterclaim are admitted.

JURISDICTION AND VENUE

6. Paragraph 6 contains conclusions of law to which no response is required.

7. Paragraph 7 contains conclusions of law to which no response is required.

8. For purposes of this action only, Plaintiffs do not contest personal jurisdiction. Plaintiffs deny the remaining allegations of paragraph 8 of the Counterclaim.

9. Plaintiffs state that this is the second of two actions involving the same patent infringement claims. There is a strong presumption that cases should proceed in the first-filed forum. *See Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1299 (Fed. Cir. 2012). Plaintiffs deny the remaining allegations of paragraph 9.

BACKGROUND

10. The allegations of Paragraph 10 of the Counterclaim are admitted.

11. The allegations of Paragraph 11 of the Counterclaim are admitted.

12. The allegations of Paragraph 12 of the Counterclaim are admitted.

13. Paragraph 13 contains conclusions of law to which no response is required. To the extent paragraph 13 contains any allegations to which a response may be required, denied.

14. Paragraph 14 contains conclusions of law to which no response is required. To the extent paragraph 14 contains any allegations to which a response may be required, denied.

15. Paragraph 15 contains conclusions of law to which no response is required. To the extent paragraph 15 contains any allegations to which a response may be required, denied.

16. Paragraph 16 contains conclusions of law to which no response is required. To the extent paragraph 16 contains any allegations to which a response may be required, denied.

17. Plaintiffs admit that the Orange Book includes Gilenya together with, among other things, the '229 patent. Plaintiffs further admit filing a Form 3542 with the FDA requesting that the '229 be listed in the Orange Book with Gilenya. Plaintiffs deny any and all remaining allegations in Paragraph 17.

18. Admitted that Ezra notified Plaintiffs that Ezra had submitted to the FDA ANDA No. 20-7945 for fingolimod capsules 0.5 mg, a drug product that is a generic version of Gilenya ("Ezra's ANDA Product"), and that the purpose of Ezra's submission of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Ezra's ANDA Product prior to the expiration of the '229 patent. Admitted also that Ezra notified Plaintiffs that, as a part of its ANDA, Ezra had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '229 patent asserting that the '229 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Ezra's ANDA Product. Plaintiffs are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 18, and therefore deny them.

19. Admitted that Ezra notified Plaintiffs by letters dated January 2, 2015 ("the Notice Letters"), that Ezra had submitted ANDA No. 20-7945 to the FDA and that Ezra

had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '229 patent asserting that the '229 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Ezra's ANDA Product. Plaintiffs deny any and all remaining allegations in Paragraph 19.

20. Admitted that the Notice Letters contained an offer of confidential access. Plaintiffs deny any and all remaining allegations of paragraph 20.

21. Admitted that Plaintiffs did not accept the offer of confidential access. Plaintiffs deny any and all remaining allegations of paragraph 21.

22. Paragraph 22 contains conclusions of law to which no response is required.

23. Admitted that Plaintiffs sued Ezra for infringement of the '229 patent on February 13, 2015. The remainder of Paragraph 23 contains conclusions of law to which no response is required.

COUNTERCLAIM COUNT 1: NON-INFRINGEMENT OF THE '229 PATENT

24. Plaintiffs incorporate each of the preceding paragraphs 1-23 as if fully set forth herein.

25. Paragraph 25 contains conclusions of law to which no response is required.

26. Paragraph 26 contains conclusions of law to which no response is required.

27. The allegations contained in Paragraph 27 of the Counterclaim are denied.

COUNTERCLAIM COUNT 2: INVALIDITY OF THE '229 PATENT

28. Plaintiffs incorporate each of the preceding paragraphs 1-27 as if fully set forth herein.

29. Paragraph 29 contains conclusions of law to which no response is required.

30. Paragraph 30 contains conclusions of law to which no response is required.

31. The allegations contained in Paragraph 31 of the Counterclaim are denied.

COUNTERCLAIM COUNT 3: INVALIDITY OF THE PATENT TERM EXTENSION

32. Plaintiffs incorporate each of the preceding paragraphs 1-31 as if fully set forth herein.

33. Paragraph 33 contains conclusions of law to which no response is required.

34. Paragraph 34 contains conclusions of law to which no response is required.

35. The allegations contained in Paragraph 35 of the Counterclaim are denied.

36. The Plaintiffs deny each and every allegation contained in the Counterclaim not specifically admitted herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment:

- a) Dismissing Ezra's Counterclaims with prejudice;

- b) Awarding Plaintiffs the relief that they requested in their Complaint; and
- c) Awarding Plaintiffs such other relief as the Court deems just and proper.

/s/ Clifford W Plunkett

Clifford W. Plunkett (Ark. Bar No. 95158)
Friday, Eldredge & Clark, LLP
3425 North Futrall Drive, Suite 103
Fayetteville, AR 72703
(479) 695-2147

plunkett@fridayfirm.com

*Attorney for Novartis AG, Novartis
Pharmaceuticals Corporation, Mitsubishi Tanabe
Pharma Corporation, and Mitsui Sugar Co., Ltd.*

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 937-7233

jane.love@wilmerhale.com
robert.trenchard@wilmerhale.com

Kevin S. Prussia
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

kevin.prussia@wilmerhale.com

Joseph M. O'Malley
Eric W. Dittmann
Yousef M. Mian
PAUL HASTINGS LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

josephomalley@paulhastings.com
ericdittmann@paulhastings.com
yousefmian@paulhastings.com

*Attorneys for Mitsubishi Tanabe Pharma
Corporation and Mitsui Sugar Co., Ltd.*

*Attorneys for Novartis AG and Novartis
Pharmaceuticals Corporation*

DATED: April 9, 2015

CERTIFICATE OF SERVICE

I, Clifford W. Plunkett, hereby certify that on April 9, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all counsel of record.

Kyle R. Wilson
Richard Blakely Glasgow
WRIGHT, LINDSEY & JENNINGS LLP
200 W. Capitol Ave., Suite 2300
Little Rock, AR 72201
Fax (501) 376-9442

kwilson@wlj.com
bglasgow@wlj.com

I further certify that on April 9, 2015, I served the foregoing via U.S. Mail on the following:

Shashank Upadhye (*pro hac vice*)
Joseph E. Cwik (*pro hac vice*)
Jonathan Kri (*pro hac vice*)
AMIN TALATI & UPADHYE
55 W. Monroe St., Suite 3400
Chicago, IL 60603

ezra-fingolimod@amintalati.com

/s/ Clifford W. Plunkett
Clifford W. Plunkett